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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,988	07/13/2005	Rainer Kraft	2002.738US	4277
67706	7590	08/17/2007		
ORGANON USA, INC. PATENT DEPARTMENT 56 LIVINGSTON AVENUE ROSELAND, NJ 07068			EXAMINER FAYYAZ, NASHMIYA SAQIB	
			ART UNIT 2856	PAPER NUMBER
			MAIL DATE 08/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/538,988

Applicant(s)

KRAFT, RAINER

Examiner

Nashmiya S. Fayyaz

Art Unit

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-18, 20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 12-16, 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinnreich et al- US Patent # 5,827,984. As to claim 12, Sinnreich et al disclose a device for simulation of dissolution of pharmaceutical dosage including an inert vessel wall and bottom (beaker 21 with floor 211) with fluid medium P, inert retainer (glass base 26) for retaining the pharmaceutical device (dosage D) and providing a passageway to the bottom (through openings 261), see fig. 3 and col. 6 lines 20 et seq. Further, it is noted that Sinnreich et al lack a teaching for the intended usage of passing a sample tube through the passageway. However, it is noted that in the Sinnreich et al device, a sample tube *is capable of* being passed through the openings 261 (which are inherently capable of allowing passage of a tube) such that it would have been obvious to one of ordinary skill in the art at the time of the invention to have collected a sample by passing the sample tube through the openings 261 depending upon where it is desired to collect the sample. Also, it is noted that Sinnreich et al

indicate that the **dissolution** of the pharmaceutical dosage form is tested and that **known analysis apparatuses** can be used, see col. 3, lines 4 et seq.

Further, it is noted that the claim recites a "vessel" for dissolution testing and the sampling tube is not a part of the vessel again suggesting intended usage. As to claim 13, the vessel is beaker and appears to be made of glass. As to claim 14, base appears to be a plate with annular openings near the middle. As to claim 15, it appears the plate (base 26) is fixed to feet 262. As to claim 16, the retainer consists of a ledge "protruding inwardly" from the vessel bottom. As to claim 20, it is noted that the embodiment of fig. 3 meets the limitation of one vessel and on the other hand note col. 9, lines 19-35 which indicates providing plural bases 26 and containers 21 and agitating devices 23 and obviously plural sampling tubes 7. As to claim 21, note refilling tubes 8.

3. Claims 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnwell et al- WO 96/28717. As to claim 12, Barnwell et al disclose a testing vessel including vessel 1 with walls and a bottom with medium 3 and retainer 6 which is a mesh or screen with passageways or openings, see fig. It is noted that Barnwell lacks a teaching for opening in the mesh are intended for a sampling tube or that the material is inert. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have realized that the openings in the screen/mesh are capable of providing the intended usage of sampling and that mesh material would have to be inert so as to avoid

interference with the testing of the solution. Again, it is noted that claim 12 merely recites a vessel for the intended usage with a sampling tube and fails to recite a combination of the two. Also, it is noted that Barnwell is a device for dissolution testing and indicates sampling on page 3. As to claim 13, usage of glass is old and well-known in the art of dissolution testing and note claim 9. As to claim 14, insert 6 appears to be in the form of a plate at the vessel wall. As to claim 15, shoulder 5 is part of the retainer which is permanently part of the vessel wall and constitutes 2 bulges of claims 16 and 17. As to claims 20 and 21, the vessel of Barnwell meets the limitation of providing one vessel and official notice is taken that provision stirring means, sampling and refilling is old and well-known in the art of dissolution testing is old and well-known such that it would have been obvious to one of ordinary skill in the art at the time of the invention to have included for full dissolution testing of the sample.

Allowable Subject Matter

4. Claim 19 is allowed.

Response to Arguments

5. Applicant's arguments filed 6/12/07 have been fully considered but they are not persuasive. Applicant has argued that 1) in the Sinnreich et al. device the size of the through-openings is small such that passageway of a sampling tube to the bottom is prevented and 2) in the Barnwell et al device the openings of the

mesh or grille are small and a sampling tube is not capable of passing through such. Such arguments are not found persuasive because it is noted that claim 12 is drawn to a vessel and the recitation of a sampling tube is merely intended usage and no size for the sampling tube is provided such that the argument that the openings in the Sinnreich et al and Barnwell et al device are "too small" is irrelevant since there are openings which inherently can allow a sampling tube (albeit small) to take a sample.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashmiya S. Fayyaz whose telephone

number is 571-272-2192. The examiner can normally be reached on Mondays and Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on 571-272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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Examiner
Art Unit 2856

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8/6/07


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